United States District Court
District of Massachusetts

In re:	)	
	)	**MDL No.**
CELEXA AND LEXAPRO MARKETING AND SALES PRACTICES LITIGATION	)	**09-02067-NMG**
	)	
DELANA S. KIOSSOVSKI and RENEE RAMIREZ,	)	
	)	
Plaintiffs,	)	
	)	**Civil Action No.**
v.	)	**14-13848-NMG**
	)	
FOREST LABORATORIES, INC., FOREST LABORATORIES, LLC and FOREST PHARMACEUTICALS, INC.,	)	
	)	
Defendants.	)	

MEMORANDUM & ORDER

GORTON, J.

This case arises out of the marketing and sales of the related anti-depressant drugs Celexa and Lexapro by defendants Forest Laboratories, Inc., Forest Laboratories, LLC and Forest Pharmaceuticals, Inc. ("defendants" or, collectively, "Forest"). Plaintiffs Delana Kiossovski ("Kiossovski") and Renee Ramirez ("Ramirez") allege that defendants engaged in a fraudulent marketing scheme designed to induce consumers to purchase Celexa and Lexapro for pediatric use.

Pending before the Court is defendants' motion to dismiss and/or to strike certain claims in the amended complaint (Docket No. 548). For the reasons that follow, that motion will be denied.

I. Background and procedural history

The background and early procedural history are set forth in this Court's earlier Memorandum & Order addressing defendants' motion to dismiss the initial complaint (Docket No. 572). The relevant factual allegations for the purposes of the pending motion are summarized below.

Celexa and Lexapro are closely-related selective serotonin reuptake inhibitor ("SSRI") anti-depressants. Forest sought to market both drugs for treating major depressive disorder ("MDD") in children and adolescents and, to that end, conducted four sets of efficacy studies. Celexa Study 94404 and Lexapro Study 15 produced negative results while Celexa Study 18 ("MD-18") and Lexapro Study 32 produced arguably positive results. The FDA-approved labels for both drugs prior to 2005 stated that "[s]afety and effectiveness in pediatric patients have not been established". Forest revised the labels in 2005 to include descriptions of the efficacy studies.

In March, 2009, the FDA reviewed the positive results in MD-18 and Lexapro Study 32, noted the chemical similarities between Celexa and Lexapro and approved Lexapro as safe and

effective in treating MDD in adolescents. Forest did not seek similar FDA approval for Celexa.

In August, 2014, former plaintiff Marlene LoConte ("LoConte") and plaintiff Kiossovski commenced this action in the Western District of Washington by filing a complaint on behalf of themselves and putative consumer classes. They alleged that Forest fraudulently promoted the pediatric and adolescent use of Celexa and Lexapro despite knowing that the drugs did not provide any clinically significant benefit over placebos in treating MDD. The case was transferred to the District of Massachusetts pursuant to a multi-district litigation assignment to this Court in October, 2014.

In June, 2015, this Court 1) allowed defendants' motion to dismiss the complaint with respect to the Racketeer Influenced and Corrupt Organizations Act ("RICO"), the Massachusetts Consumer Protection Act, M.G.L. c. 93A ("Chapter 93A") and unjust enrichment claims brought by LoConte and 2) denied the motion with respect to the RICO, Washington Consumer Protection Act ("CPA") and unjust enrichment claims brought by Kiossovski.

Plaintiffs amended the complaint in January, 2016 by replacing LoConte with Ramirez as the second plaintiff and putative class representative. The amended complaint raised two RICO claims by Kiossovski and Ramirez, an unjust enrichment claim by both plaintiffs and a CPA claim by Kiossovski.

II. Motion to dismiss

Defendants move to dismiss Ramirez's individual claims and the putative class action claims relating to Lexapro and adolescent use.

A. Legal standard

To survive a motion to dismiss, a complaint must contain sufficient factual matter to state a claim to relief that is plausible on its face. Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). The Court must accept all factual allegations in the complaint as true and draw all reasonable inferences in the plaintiff's favor. Santiago v. Puerto Rico, 655 F.3d 61, 72 (1st Cir. 2011). Threadbare recitals of the legal elements, supported by mere conclusory statements, do not suffice to state a cause of action. Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). A complaint does not state a claim for relief where the well-pled facts fail to warrant an inference of any more than the mere possibility of misconduct. Id. at 679.

B. Application

1. Ramirez's RICO claims

Defendants first move to dismiss Ramirez's RICO claims for failure to state a claim. They assert that her claims are time-barred under the statute of limitations.

The statute of limitations for civil RICO claims is four years after the plaintiff discovers or should have discovered

the injury. See Rotella v. Wood, 528 U.S. 549, 553 (2000). The limitations period commences when the plaintiff "knew or should have known of his injury." Lares Grp., II v. Tobin, 221 F.3d 41, 44 (1st Cir. 2000).

The amended complaint alleges that Ramirez purchased Celexa for her eight-year-old son starting in February, 2003 and continuing through April, 2004 but that Celexa did not effectively treat his pediatric depression. Ramirez also asserts that she purchased Lexapro for her son from May, 2004 through his twelfth birthday in January, 2007. She continued buying Lexapro for her son until he stopped using it in 2011 due to side effects such as muscle spasms and difficulty concentrating in school. The amended complaint declares that Ramirez first learned in February, 2014 that "Lexapro had not been proven effective for children" and first realized, "[w]ith the benefit of hindsight", that this was consistent with her prior observations that Lexapro was ineffective for her son. Plaintiffs allege that Ramirez did not discover, and had no reason to discover, her RICO injury until 2014.

Defendants respond that Ramirez's RICO claims are time-barred because she first became aware that Lexapro was ineffective with respect to her son in January, 2007. They argue that she thus discovered her RICO injury more than four years before the initiation of this action in 2014. They assert

that the doctrine of fraudulent concealment does not toll the statute of limitations because the amended complaint fails to allege that Ramirez diligently investigated the potential inefficacy of Lexapro by reading, for instance, either the Lexapro drug label or any of the numerous public announcements of Lexapro's inefficacy.

Plaintiffs respond that, although Ramirez believed that Lexapro was ineffective for her son in 2007, she did not know, and had no reason to know, that Lexapro was ineffective in children generally until she learned about the negative efficacy studies in 2014. They contend that the doctrine of fraudulent concealment tolls the statute of limitations because the amended complaint alleges that 1) defendants wrongfully concealed their fraudulent marketing practices, 2) Ramirez did not discover her RICO injury within the limitations period and 3) she acted diligently and did not have reason to discover her RICO injury, see Berkson v. Del Monte Corp., 743 F.2d 53, 55 (1st Cir. 1984).

The first step for the Court is to identify the nature of Ramirez's asserted RICO injury. The amended complaint alleges that defendants' misrepresentations prevented her from making an informed decision which caused her to buy Lexapro that she otherwise would not have bought for her son. Plaintiffs clarify in their opposition memorandum that Ramirez's injury stemmed from her belief that Celexa and Lexapro were effective with

respect to children in general, not a belief that they would be effective for her son specifically.

The asserted injury, therefore, consists of payments for prescriptions of Celexa and Lexapro that she made for pediatric use as a result of defendants' alleged misconduct which precluded her from making an informed decision as to efficacy. Her injury qualifies as a RICO injury because she claims that 1) she bought Celexa and Lexapro as a result of defendants' misrepresentations of efficacy, 2) Lexapro was ineffective for her son and thus 3) she bought products with undisclosed risks that actually materialized with respect to her son. See In re Celexa & Lexapro Mktg. & Sales Practices Litig., 2015 WL 3751422, at *6 (D. Mass. June 15, 2015) ("LoConte")("Because LoConte does not contend that Lexapro was ineffective as to her son, her alleged RICO injury is inadequate because it is akin to a lack of informed decision before purchasing a product with undisclosed risks that never appear.").

The inquiry before this Court is whether, taking all of the factual allegations in the amended complaint as true, plaintiffs have pled facts sufficient to support a finding that Ramirez did not discover, or have reason to discover, her RICO injury, i.e., payment for drugs that had no pediatric efficacy, before the accrual of the limitations period.

After considering the allegations in the light most favorable to plaintiffs, the Court is satisfied that plaintiffs have set forth facts sufficient to support a finding that Ramirez, as a consumer, did not discover her RICO injury until 2014 and had no reason for discovering it sooner. The Court declines to make a factual determination as to whether Ramirez actually discovered, or reasonably should have discovered, her RICO injury prior to 2014. See id. at *5 (finding that "the running of the [statute of limitations] is usually a question for the jury"); In re Celexa & Lexapro Mktg. & Sales Practices Litig., 65 F. Supp. 3d 283, 289 (D. Mass. 2014)("Painters I")("[T]he Court will leave the determination of whether plaintiff should have discovered its injury as of 2005 to the finder of fact.").

Accordingly, the motion to dismiss Ramirez's RICO claims as time-barred will be denied.

2. Ramirez's unjust enrichment claim

Defendants move to dismiss Ramirez's claim for unjust enrichment on the ground that she "fails to state a viable RICO claim, or any other actionable wrong". That argument is inapposite in light of the finding that her RICO claims survive dismissal with respect to the statute of limitations.

Accordingly, defendants' motion to dismiss her unjust enrichment claim will be denied.

3. Putative Lexapro class action claims with respect to adolescent use

Defendants seek to dismiss the putative class action claims that Lexapro was ineffective with respect to patients between the ages of 12 and 17. They contend that the amended complaint "concedes" that the FDA approved Lexapro as effective for adolescent use in 2009 which precludes plaintiffs from plausibly alleging that Lexapro is medically ineffective for adolescent patients. Defendants move to dismiss those putative class action claims for failure to state a claim.

The Court finds that argument unpersuasive. Plaintiffs allege that 1) Ramirez bought Lexapro for her son as a result of defendants' misconduct, 2) her son used Lexapro both before and after he turned 12 years old and 3) Lexapro was ineffective at treating her son's depression. Such allegations are sufficient to plead a RICO injury in support of a RICO claim. That conclusion is in line with an earlier finding by this Court that former plaintiff LoConte could not allege a RICO injury because she admitted that the FDA approved Lexapro as effective for adolescents in 2009 without also contending that Lexapro was ineffective as to her own child. See LoConte, 2015 WL 3751422, at *6.

Defendants advance no other arguments for dismissing the putative class action claims with respect to the adolescent use of Lexapro.

The putative class action claims that Lexapro was ineffective for adolescent use thus survive dismissal. The Court will leave to the jury the task of weighing the totality of the evidence which in this case includes an FDA determination that Lexapro is effective for adolescent use and Ramirez's observations that Lexapro was ineffective for her son. Likewise, the Court declines to evaluate or review the validity of the FDA's decision that certain clinical studies established the efficacy of Celexa and Lexapro for adolescent use. See In re Celexa & Lexapro Mktg. & Sales Practices Litig., 2016 WL 3102004, at *11 (D. Mass. June 2, 2016)("Painters II") (citing In re Celexa & Lexapro Mktg. & Sales Practice Litig., 779 F.3d 34, 41 (1st Cir. 2015) ("Marcus")).

Accordingly, the Court will deny defendants' motion to dismiss the putative class action claims alleging that Lexapro was ineffective for patients between the ages of 12 and 17.

III. Motion to strike class allegations

Defendants move to strike all of the Celexa and Lexapro class allegations pursuant to Fed. R. Civ. P. 12(f) and 23(d)(1)(D).

A. Legal standard

Rule 12(f) permits a court to strike class allegations from the complaint if it is "obvious" from the pleadings that "the proceeding cannot possibly move forward on a classwide basis". Manning v. Boston Med. Ctr. Corp., 725 F.3d 34, 59 (1st Cir. 2013). Striking class allegations under Rule 12(f) is a drastic remedy that is disfavored in practice because

> it requires a reviewing court to preemptively terminate the class aspects of . . . litigation, solely on the basis of what is alleged in the complaint, and before plaintiffs are permitted to complete the discovery to which they would otherwise be entitled on questions relevant to class certification.

Id. The more typical course is to "await the development of a factual record" before deciding whether to allow the case to proceed as a class action. Id.

Rule 23 authorizes a court to issue orders requiring "that the pleadings be amended to eliminate allegations about [the] representation of absent persons". Fed. R. Civ. P. 23(d)(1)(D).

B. Application

Defendants seek to strike the class allegations now, before plaintiffs move for class certification, because they claim that plaintiffs will not be able to satisfy the predominance requirement in Fed. R. Civ. P. 23(b)(3). They assert that the case cannot proceed on a class-wide basis because resolution of the issues concerning the statute of limitations, injury and

causation will require individualized determinations that overwhelm the class-wide issues. They also point out that the parties in the multi-district litigation have engaged in seven years of discovery and the Court has already denied the certification of multiple consumer classes in those related cases.

The Court concludes that striking the class allegations at this preliminary stage would, however, be premature. The Court will consider the propriety of allowing the litigation to proceed as a class action after plaintiffs have had an opportunity to submit their anticipated motion for class certification.

Accordingly, defendants' motion to strike the class allegations will be denied.

ORDER

For the foregoing reasons, defendants' motion to dismiss and/or to strike certain claims in the amended complaint (Docket No. 548) is **DENIED.**

So ordered.

/s/ Nathaniel M. Gorton
Nathaniel M. Gorton
United States District Judge

Dated June 9, 2016